Protocol

Subtalar Arthroereisis

(701104)

Medical Benefit		**Effective Date**: 10/01/08	**Next Review Date**: 11/20
Preauthorization	No	**Review Dates**: 07/07, 07/08, 09/09, 03/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With flatfoot	Interventions of interest are: • Subtalar arthroereisis	Comparators of interest are: • Alternative surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With talotarsal joint dislocation	Interventions of interest are: • Subtalar arthroereisis	Comparators of interest are: • Alternative surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

DESCRIPTION

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

SUMMARY OF EVIDENCE

For individuals who have flatfoot or talotarsal joint dislocation who receive STA, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. Relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (n=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to STA, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of particular importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Subtalar arthroereisis is considered **investigational**.

BACKGROUND

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The MBA implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

REGULATORY STATUS

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, and are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Table 1. Representative Subtalar Implant Devices Cleared by FDA[a]

Device	Manufacturer	Date Cleared	510(k) No.
Subtalar MBA®	Integra LifeSciences	Jul 1996	K960692
OsteoMed Subtalar Implant System	OsteoMed	Aug 2003	K031155
BioPro Subtalar Implant	BioPro	Sep 2004	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	Sep 2004	K042030
MBA resorb Implant	Kinetikos Medical	Sep 2005	K051611
Metasurg Subtalar Implant	Metasurg	May 2007	K070441
Subtalar Implant	Biomet Sports Medicine	Jul 2007	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	Jan 2008	K071456
Trilliant Surgical Subtalar Implant	Trilliant Surgical	Feb 2011	K103183
Metasurg Subtalar Implant	Metasurg	Aug 2011	K111265
NuGait™ Subtalar Implant System	Ascension Orthopedic	Aug 2011	K111799
Disco Subtalar Implant	Trilliant Surgical	Dec 2011	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	Dec 2011	K112658
IFS Subtalar Implant	Internal Fixation Systems	Dec 2011	K113399
The Life Spine Subtalar Implant System	Life Spine	Jun 2016	K160169

FDA: Food and Drug Administration.

[a]FDA 510(k) database search product code HWC (03/08/18).

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Chong DY, Macwilliams BA, Hennessey TA, et al. Prospective comparison of subtalar arthroereisis with lateral column lengthening for painful flatfeet. J Pediatr Orthop B. Jul 2015;24(4):345-353. PMID 25856275.
2. Metcalfe SA, Bowling FL, Reeves ND. Subtalar joint arthroereisis in the management of pediatric flexible flatfoot: a critical review of the literature. Foot Ankle Int. Dec 2011;32(12):1127-1139. PMID 22381197.
3. Graham ME, Jawrani NT, Chikka A. Extraosseous talotarsal stabilization using HyProCure(R) in adults: a 5-year retrospective follow-up. J Foot Ankle Surg. Jan-Feb 2012;51(1):23-29. PMID 22196455.
4. Vedantam R, Capelli AM, Schoenecker PL. Subtalar arthroereisis for the correction of planovalgus foot in children with neuromuscular disorders. J Pediatr Orthop. May-Jun 1998;18(3):294-298. PMID 9600551.
5. Nelson SC, Haycock DM, Little ER. Flexible flatfoot treatment with arthroereisis: radiographic improvement and child health survey analysis. J Foot Ankle Surg. May-Jun 2004;43(3):144-155. PMID 15181430.
6. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. Foot Ankle Int. Jan 2006;27(1):9-18. PMID 16442023.
7. Cicchinelli LD, Pascual Huerta J, Garcia Carmona FJ, et al. Analysis of gastrocnemius recession and medial column procedures as adjuncts in arthroereisis for the correction of pediatric pes planovalgus: a radiographic retrospective study. J Foot Ankle Surg. Sep-Oct 2008;47(5):385-391. PMID 18725117.
8. Brancheau SP, Walker KM, Northcutt DR. An analysis of outcomes after use of the Maxwell-Brancheau Arthroereisis implant. J Foot Ankle Surg. Jan-Feb 2012;51(1):3-8. PMID 22196453.
9. Bresnahan PJ, Chariton JT, Vedpathak A. Extraosseous talotarsal stabilization using HyProCure(R): preliminary clinical outcomes of a prospective case series. J Foot Ankle Surg. Mar-Apr 2013;52(2):195-202. PMID 23313499.
10. Scher DM, Bansal M, Handler-Matasar S, et al. Extensive implant reaction in failed subtalar joint Arthroereisis: report of two cases. HSS J. Sep 2007;3(2):177-181. PMID 18751791.
11. Saxena A, Nguyen A. Preliminary radiographic findings and sizing implications on patients undergoing bioabsorbable subtalar arthroereisis. J Foot Ankle Surg. May-Jun 2007;46(3):175-180. PMID 17466243.
12. Cook EA, Cook JJ, Basile P. Identifying risk factors in subtalar arthroereisis explantation: a propensity-matched analysis. J Foot Ankle Surg. Jul-Aug 2011;50(4):395-401. PMID 21708340.
13. National Institute for Health and Care Excellence (NICE). Sinus Tarsi Implant Insertion for Mobile Flatfoot [IPG305]. 2009; https://www.nice.org.uk/guidance/IPG305. Accessed March 13, 2019.
14. Harris EJ, Vanore JV, Thomas JL, et al. Clinical Practice Guideline Pediatric Flatfoot Panel: American College of Foot and Ankle Surgeons (ACFAS). Diagnosis and treatment of pediatric flatfoot. J Foot Ankle Surg. Nov-Dec 2004;43(6):341-373. PMID 15605048.
15. Lee MS, Vanore JV, Thomas JL, et al. Clinical Practice Guideline Adult Flatfoot Panel: American College of Foot and Ankle Surgeons (ACFAS). Diagnosis and treatment of adult flatfoot. J Foot Ankle Surg. Mar-Apr 2005;44(2):78-113. PMID 15768358.